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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,787	10/27/2000	Victor Levy	50824-2-2-1	6687

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EXAMINER

PASS, NATALIE

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/698,787	Applicant(s) LEVY, VICTOR	
	Examiner Natalie A. Pass	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2 June 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2 June 2005 has been entered. The Information Disclosure Statement filed 2 June 2005 has been entered and considered.
2. This communication is in response to the Request for Continued Examination and amendment filed 2 June 2005. Claims 1-11 have been cancelled. Claims 12-15 have been newly added. Claims 12-15 remain pending.

Specification

3. The amendment filed 2 June 2005 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. "New matter" constitutes any material which meets the following criteria:
 - a) It is added to the disclosure (either the specification, the claims, or the drawings) after the filing date of the application, and

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b) It contains new information which is neither included nor implied in the original version of the disclosure. This includes the addition of physical properties, new uses, etc. The added material which is not supported by the original disclosure is as follows:

- " an independent variable is generated for each array for each possible post test outcome nearly simultaneously in response to each patient answer or test result," as disclosed in claim 12, lines 23-25.

In particular, Applicant does not point to, nor was the Examiner able to find, any support for this newly added language within the specification as originally filed on 27 October 2000. As such, Applicant is respectfully requested to clarify the above issues and to specifically point out support for the newly added limitations in the originally filed specification and claims.

Applicant is required to cancel the new matter in the reply to this Office Action.

4. If Applicant continues to prosecute the application, revision of the specification and claims to present the application in proper form is required. While an application can be amended to make it clearly understandable, no subject matter can be added that was not disclosed in the application as originally filed on 27 October 2000.

5. The objection to the amendment filed 10 September 2004 under 35 U.S.C. 132 because it introduced new matter into the disclosure is hereby withdrawn due to the response filed 2 June 2005.

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Claim Objections

6. The objection to the claims under 37 CFR 1.126 and 37 CFR 1.121 (c) is hereby withdrawn due to the response filed 2 June 2005.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Newly added claims 12-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A) Independent claim 12 recites limitations that are new matter, as discussed above, and is therefore rejected.

(B) Claims 13-15 incorporate the features of independent claim 12, through dependency and are also rejected.

9. The rejections of claims 1 and 8-11 under 35 U.S.C. 112, first paragraph for introducing new matter is hereby withdrawn due to the response filed 2 June 2005.

10. The rejections of claims 1, 8 and 10 under 35 U.S.C. 112, second paragraph, for being indefinite is hereby withdrawn due to the response filed 2 June 2005.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iliff et al.,

U.S. Patent Number 6, 206, 829 in view of Blinowska article: "Diagnostica-A Bayesian

Decision-Aid System-Applied to Hypertension Diagnosis," 1993, URL:

:<<http://ieeexplore.ieee.org/iel5/10/5657/00216406.pdf?arnumber=216406>>, hereinafter known

as Diagnostica, and further in view of Sonis article: "How to Use and Interpret Interval

Likelihood Ratios," June 1999, URL:

<<http://www.stfm.org/fmhub/Fullpdf/june99/rs.pdf>>hereinafter known as Sonis.

(A) As per claim 12, Iliff teaches a web-based system for facilitating diagnosis of medical symptoms (Iliff; Figure 25a, Figure 30, column 68, lines 30-60) comprising:

(a) an automated database that is a real-time, web-based system that includes statistically accrued data that is input from multiple sources via an "HTML form" (reads on "common web-based system template") (Iliff; Figure 25a, Figure 30, column 68, line 6 to column 69, line 32, column 70, lines 1-29);

the “HTML form” (reads on “common web-based system template”) providing a medium for entering data into the database that includes actual diagnoses and patient symptoms and information from patient populations (Iliff; Figure 25a, Figure 30, column 68, line 6 to column 69, line 32, column 70, lines 1-29, column 74, lines 45-56); and

(c) an independent variable is generated for each array for each possible post test outcome nearly simultaneously in response to each patient answer or test result (Iliff; see at least Figure 30, column 4, line 45 to column 5, line 17, column 68, line 61 to column 69, line 32, column 76, lines 55-59).

Although Iliff teaches a plurality of possible post-test diagnostic outcomes, each outcome indicating a possible disease and probability for the disease (Iliff; column 39, line 29 to column 40, line 67), Iliff fails to explicitly disclose the common template being used to generate a matrix and reporting the possible post-test outcomes to a user as a list of diagnostic probabilities ranked from the most likely to the least likely of possible diagnoses for a patient under examination, and each possible post-test outcome of the plurality of possible post-test diagnostic outcomes in the matrix being generated from an array of mathematical factors that are based on patient symptoms and information, and with each of the other factors in the array being input as an independent variable that is produced from answers to individual patient questions or results from diagnostic tests for that patient and indicates the likelihood of a post-test diagnostic outcome based on past data entered via the common web-based template and wherein the factors in the array are multiplied together to produce the possible post-test diagnostic outcome that indicates a possible disease and probability for the disease.

However, the above features are well-known in the art, as evidenced by Diagnostica.

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In particular, Diagnostica teaches the common template being used to generate a matrix (Diagnostica; page 230, column 1, paragraph 3 to page 231, column 1, paragraph 5);

reporting the possible post-test outcomes to a user as a list of diagnostic probabilities ranked from the most likely to the least likely of possible diagnoses for a patient under examination (Diagnostica; Figure 5, page 231, column 1, paragraph 5, page 234, column 2, paragraphs 1-2);

(b) each possible post-test outcome of the plurality of possible post-test diagnostic outcomes in the matrix being generated from an array of mathematical factors that are based on patient symptoms and information (Diagnostica; Figure 2, page 232, column 1, paragraph 2);

with each of the other factors in the array being input as an independent variable that is produced from answers to individual patient questions or results from diagnostic tests for that patient and indicates the likelihood of a post-test diagnostic outcome based on past data entered via the common web-based template (Diagnostica; Abstract, Figure 4, page 230, column 1, paragraph 3 to column 2, paragraph 12);

wherein the factors in the array are multiplied together to produce the possible post-test diagnostic outcome that indicates a possible disease and probability for the disease (Diagnostica; page 235, column 1, paragraph 3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Iliff to include the claimed limitations, as taught by Diagnostica, with the motivations of evaluating multiple experimental parameters that have been taken into consideration, all of them available during the first medical examination, to aid in

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making a decision and “to choose, for a given patient, one of K possible diagnoses”

(Diagnostica; Abstract, page 230, column 2, lines 14-15).

Iliff fails to explicitly disclose one of the factors being a pre-test odds factor. However, the above features are well-known in the art, as evidenced by Sonis.

In particular, Sonis teaches one of the factors being a pre-test odds factor (Sonis; page 435, column 1, paragraph 4 to column 2, paragraph 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Iliff to include the claimed limitations, as taught by Sonis, with the motivations of capturing the magnitude of abnormality of test results and aid in making clinical decisions involving diagnostic tests (Sonis; Abstract, page 437, column 1, paragraph 3).

(B) As per claims 13-15, Iliff, Diagnostica, and Sonis teach a system as analyzed and discussed in claim 12 above

wherein the independent variable that is produced from answers to individual patient questions or results from diagnostic tests is generated by creating a statistical likelihood ratio that results in a mathematical likelihood ratio factor (Sonis; Figure 1, page 434, column 1, paragraph 1 to column 2, paragraph 1), the likelihood ratio factor being multiplied to the pre-test odds factor so that the likelihood ratio either increases or decreases the value of the pre-test odds factor depending on the value of the likelihood ratio factor (Sonis; page 435, column 1, paragraph 4 to column 2, paragraph 2);

wherein the “HTML form” (reads on “common template”) is used to update the statistically-accrued data in the web-based system following generation of the matrix that

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includes the plurality of post-test diagnostic test outcomes (Iliff; Figure 25a, Figure 30, Items 2358, 2360, column 4, lines 10-13, column 12, lines 46-51, column 57, lines 13-15, column 68, line 6 to column 69, line 32, column 70, lines 1-29, column 74, lines 45-56), (Diagnostica; page 230, column 1, paragraph 3 to page 231, column 1, paragraph 5); and

wherein the plurality of possible post-test diagnostic outcomes are reported as ranked probabilities (Diagnostica; Figure 5, page 231, column 1, paragraph 5, page 234, column 2, paragraphs 1-2).

The motivations for combining the respective teachings of Iliff, Diagnostica, and Sonis are as given in the rejection of claim 12 above, and incorporated herein.

Response to Arguments

13. Applicant's arguments on pages 4-13 of the response filed 12 June 2005 with respect to newly added claims 12-15 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied references Lapointe et al., U.S. Patent Number 6, 556, 977, Anderson, et al., U.S. Patent Number 6, 267, 722, Thiesson et al., U.S. Patent Number 6, 336, 108, Baker, U.S. Patent Number 6, 076, 083, Breese et al U.S. Patent Number 6, 185, 534 and Feldman et al., U.S. Patent Number 5, 626, 140, and the articles teach the environment of utilizing past knowledge and statistical analysis for diagnosis of medical symptoms.

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Blinowska, A. et al., Bayesian Statistics as Applied to Hypertension Diagnosis. IEEE Transactions on Biomedical Engineering. Vol. 38, No. 7, 1991. [Retrieved on August 16, 2005]. Retrieved from the Internet: URL: <<http://ieeexplore.ieee.org/iel1/10/2725/00083571.pdf>>.

Hamilton, R. FDA Examining Computer Diagnosis. FDA Consumer magazine. September 1995. [Retrieved on August 16, 2005]. Retrieved from the Internet: URL: <http://www.fda.gov/fdac/features/795_compdiag.html>.

Lemaire, J. et al., Effectiveness of the Quick Medical Reference as a diagnostic tool. Canadian Medical Association Journal. September 1999. [Retrieved on August 16, 2005]. Retrieved from the Internet: URL:

<http://epe.lac-bac.gc.ca/100/201/300/cdn_medical_association/cmaj/vol-161/issue-6/pdf/pg725.pdf>.

Products - Iliad 4.5 page. A.D.A.M. Software website. February 1998. [Retrieved on August 16, 2005]. Retrieved from the Internet: URL: <http://web.archive.org/web/19980203083438/http://www.adam.com/hc_iliad.html>.

15. Any response to this action should be mailed to:

Commissioner of Patents and Trademarks

Washington D.C. 20231

or faxed to: **(571) 273-8300.**

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For informal or draft communications, please label
"PROPOSED" or "DRAFT" on the front page of the communication
and do NOT sign the communication.

After Final communications should be labeled "Box AF."

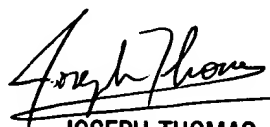
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Pass whose telephone number is (571) 272-6774. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 6:30 PM. The examiner can also be reached on alternate Fridays.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (571) 272-3600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Natalie A. Pass

August 16, 2005


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600